

rejections are in error and the rejections are, therefore, traversed.

2. Claims 1-11 have been rejected under 35 U.S.C. §103(a) as being obvious over Watmough et al. in view of Chervitz. In particular, the Examiner asserts that

Watmough et al. disclose a means and method of applying ultrasound treatment wherein a temperature sensing visual indicator is in contact with the treated tissue, wherein temperature of the skin is indicated by color changes, column 3, lines 21-23 and 30-33. The patent teaches a liquid crystal device that detects the temperature of the skin via color changes. In addition Watmough et al. disclose that frequency of the ultrasound is altered to alter depth and temperature distribution, column 3, lines 37-44. In regard to claim 11 Watmough et al. disclose a computer simulation for determining skin temperature, ultrasound absorption, thermal conduction, and different power settings of the transducer on the temperature distribution inside the tissue during local hyperthermia.

Watmough et al. differs from the claimed invention in that a securing mechanism via an adhesive backing is not addressed. Other features of the strip that are not addressed in Watmough et al. include the strip further comprising a plastic sandwich, colored background, and character display. Also Watmough et al. does not teach a color change at a predetermined or threshold temperature.

Chervitz discloses a visual indicator with an adhesive backing, and comprising of a plastic sandwich, colored backing, and displaying numeric characters indicative of temperature change. Chervitz teaches a visual indicator adapted to be disposed on the skin or surface of the body that changes color and displays characters at the threshold temperature of the specific temperature range of the crystal indicator, column 1 line 16. See abstract, column 1 lines 14-17, and column 2 lines 4-9. The patent further teaches that the color spectrum of each liquid crystal indicator are responsive to a different specific temperature range, and the liquid crystal indicator being invisible at temperatures below the threshold temperature. In other words each liquid crystal indicator changes color only at this threshold or predetermined temperature, each indicator having a specific

temperature range, column 2 lines 4-17. In addition the adhesive visual indicator of Chervitz is capable of being used with an ultrasound treatment because it is adapted to be disposed on the skin or surface of the body to provide color change due to tissue temperature change.

It would have been obvious at the time the invention was made to a person of ordinary skill in the art to determine an average depth of penetration of the ultrasound for the selected frequency, column 5, lines 13-16. Average is construed to mean typical or normal in this claim. Watmough et al. teaches a method that is applicable for predicting affected tissue characteristics due to ultrasound treatment. It would have been obvious to a person of ordinary skill in the art to use the temperature-detecting skin patch of Chervitz because it provides means for monitoring the ultrasound treatment via detecting when threshold temperature has been reached. Since Watmough et al. already discloses a means of detecting the skin temperature to monitor the ultrasound treatment, it would have been obvious to one of ordinary skill in art to use the skin surface patch of Chervitz because it is an alternative means of detecting skin temperature. Also it would have been obvious for a person of ordinary skill in the art to substitute alphanumeric characters for numeric character. Chervitz already discloses a means for displaying a temperature change using characters. Therefore the characters could either be numeric or alphanumeric and in addition any message could be displayed using the alphanumeric characters. Further it would have been obvious to indicate a visual change only at a predetermined temperature in order to monitor ultrasound treatment.

It is noted first, that Watmough et al. states that "the skin temperature is maintained at 42° C (by placing a warm-water bath on the skin)" (Watmough et al., col. 9, lines 51-52) and a "warm water bath . . . maintains a constant surface temperature to minimize any fluctuation caused by the physical environment" (Watmough et al., col. 11, lines 22-25). To suggest that Watmough et al. could be modified using the fever thermometer of Chervitz would impermissibly change a principle of

operation of Watmough et al. More specifically, if the surface temperature of the skin of the patient were maintained at a constant temperature as taught by Watmough et al., then the fever thermometer of Chervitz could not work as suggested by the Examiner.

Further, "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious". *In re Ratti*, 270 F2d 810, 123 USPQ 349 (CCPA 1959), MPEP §2143.02. Since the modification to Watmough et al. proposed by the Examiner would change the principle of operation of Watmough et al., the teachings of the references of Watmough and Chervitz are not sufficient to render the claims *prima facie* obvious. Since the references are not sufficient to render the claims *prima facie* obvious, the rejection is improper and should be withdrawn.

It is noted next, that the invention is drawn to the method step of (and apparatus for) "determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached". As described "An ultrasonic penetration depth may be selected using a frequency control 22 on the source 12 based upon the thickness and mass to be treated . . . Using a specific heat of the area and power output of the transducer 14, a rate of rise of temperature may be

determined for a particular dosage limit . . . By knowing a distance from the surface where heat localization will occur, a predicted temperature of the surface may be determined for the dosage limit" (specification, page 6, lines 2-11).

In contrast, Watmough et al. makes no attempt to "determine a temperature rise which the body portion will experience when a dosage limit of the ultrasonic treatment has been reached" and instead "maintains a constant surface temperature to minimize any fluctuation caused by the physical environment" (Watmough et al., col. 5, lines 42-44; col. 9, lines 51-52; col. 11, lines 23-25). More to the point, Watmough et al. is "adapted to provide an output signal indicative of temperature values adjacent a target tumor" (Watmough et al., col. 2, lines 48-50).

Chervitz is simply drawn to fever thermometers. As such, Chervitz provides absolutely no teaching or suggestion of the step of "determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached".

Since the combination of Watmough et al. and Chervitz fails to provide any teaching or suggestion of "determining a temperature rise which the body portion will experience when a dosage limit of the ultrasound treatment has been reached", the combination fails to teach each and every claim limitation as required by MPEP §2143.03. Since the combination fails to teach

each and every claim limitation, the prima facie case of obviousness has not been made. Since the prima facie case of obviousness has not been made, the rejection is improper and should be withdrawn.

It is noted next, that the claimed invention is drawn to "disposing on a surface of the body portion an indicator adapted to provide a visual change only at the predetermined temperature". It is believed that the combination of Watmough et al. and Chervitz also fail to teach or suggest this claim element.

For example, Watmough et al. explicitly states that "the skin overlaid by the bath may have in contact therewith a liquid crystal device to indicate the temperature of the skin by colour changes" (Watmough et al., col. 3, lines 30-32). Since the Watmough et al. provides "colour changes" based upon temperature, it cannot "provide a visual change only at the predetermined temperature".

Chervitz suffers from the same problem. More specifically, Chervitz explicitly states that "the web being provided with a . . . plurality of numerical display areas . . . each display area . . . being responsive to a different specific temperature range" (Chervitz, Abstract, lines 3-9). Since the Chervitz device has a number of display areas that are each responsive to a different temperature range, the Chervitz device

cannot be said to "provide a visual change only at the predetermined temperature".

Further, "it is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art". In re Wesslau 353 F.2d 238, 147 USPQ 391 (CCPA 1965). As would be clear to a person of skill in the art, the combination of Watmough et al. and Chervitz teaches of devices that provide visual indications at a number of predetermined temperatures. As such, the combination does not teach or suggest "an indicator adapted to provide a visual change only at the predetermined temperature".

Since the combination of Watmough et al. and Chervitz fails to provide any teaching or suggestion of "disposing on a surface of the body portion an indicator adapted to provide a visual change only at the predetermined temperature", the combination fails to teach each and every claim limitation as required by MPEP §2143.03. Since the combination fails to teach each and every claim limitation, the prima facie case of obviousness has not been made. Since the prima facie case of obviousness has not been made, the rejection is improper and should be withdrawn.

In addition, claim 1 is drawn to "means adapted to be disposed on the portion for providing a color change only at a predetermined temperature when a dosage limit of the ultrasound treatment has been reached". During lipoplasty "A surgeon performing such a procedure has no feedback on how much energy is delivered over any given time span within a given area of treatment" (specification, page 2, lines 14-16). Under illustrated embodiments of the invention "The thermal indicators 20 may be fabricated with a colored background . . . (e.g., "DOSAGE REACHED") may be printed on the background and may only be revealed when the portion 18 exceeds the calibrated temperature of the indicator 20" (specification, page 4, lines 13-20).

As described, a number of thermal indicators 20 may be provided, each in the form of "a thermally reactive film (e.g., a thermochromatic film) fabricated to change color or opacity at a predetermined temperature" (specification, page 4, lines 3-6). In use, "a mass of a fat layer may be determined for a particular area to be treated . . . Using a specific heat of the area and power output of the transducer 14, a . . . temperature may be determined for a dosage limit" (specification, page 5, lines 1-11). For example, "in the case of pretreatment for liposuction (i.e., to facilitate fat dissociation) it has been found that indicators calibrated to 1 °C above a normal body temperature works well for detecting (and limiting) ultrasonic dosage for

layers of fat of an intermediate thickness (e.g., one inch) . . . A higher temperature (e.g., 1.25-1.5 °C may be used for thicker layers" (specification, page 6, lines 14-22). Further, "To provide a measure of dosage, one or more temperature indicators 20 may be placed in the treatment area . . . The indicators 20 may be calibrated to a single temperature or a number of different indicators 20 may be used with each calibrated to a different temperature" (specification, page 7, lines 3-7). In addition, "As the nurse moves the ultrasound applicator 14 over the grid, the indicators 20 will change color, upon reaching the appropriate temperature . . . As the nurse removes each indicator and moves on to the next grid, the entire region maybe optimally dosed" (specification, page 7, lines 23-28).

In contrast, Watmough et al. and Chervitz teach of liquid crystal temperature devices providing visual changes in a number of different temperatures (Watmough et al., col. 3, lines 30-32); Chervitz, col. 3, lines 25-32). As such, the Watmough et al. and Chervitz devices are structurally different than the claimed invention.

Further, claim 1 is a means-plus-function claim. An examiner is "required by statute to look to . . . specification and construe the 'means' language recited in . . . claim 1 as limited to corresponding structure disclosed in the specification and equivalents thereof". In re Donaldson Co., Inc., 16 F.3d 1189 (Fed. Cir. 1994). The combination of Watmough et al. and

Chervitz clearly fails to provide comparable structure to that described and shown in the specification.

Since the combination of Watmough et al. and Chervitz fails to teach each and every claim limitation as required by MPEP §2143.03, the prima facie case of obviousness has not been made. Since the prima facie case of obviousness has not been made, the rejection is improper and should be withdrawn.

3. Claims 12-17 have been rejected as being obvious over Watmough et al. in view Chervitz and Cohen. However, Cohen also fails to provide any teaching or suggestion of providing a color or opacity change only when a dosage limit of the ultrasonic treatment has been reached. As such, the combination of Watmough et al., Chervitz and Cohen fails to teach each and every claim limitation. Since the combination fails to teach each and every claim limitation, the prima facie case of obviousness has not been made. Since the prima facie case of obviousness has not been made, the rejection is improper and should be withdrawn.

4. Claim 18 has been rejected as being obvious over Watmough et al. in view of Chervitz and Behnke et al. However, Behnke et al. also fails to provide any teaching or suggestion of providing a color or opacity change only when a dosage limit of the ultrasonic treatment has been reached. As such, the combination of Watmough et al., Chervitz and Behnke et al. fails

to teach each and every claim limitation. Since the combination fails to teach each and every claim limitation, the prima facie case of obviousness has not been made. Since the prima facie case of obviousness has not been made, the rejection is improper and should be withdrawn.

5. Allowance of claims 1-18, as now presented, is believed to be in order and such action is earnestly solicited. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to telephone applicant's undersigned attorney.

Respectfully submitted,

WELSH & KATZ, LTD.

By



Jon P. Christensen
Registration No. 34,137

October 1, 2001
WELSH & KATZ, LTD.
120 South Riverside Plaza
22nd Floor
Chicago, Illinois 60606
(312) 655-1500